



DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Start-up Exclusive License: Scopolamine For The Treatment Of Depression And Anxiety

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209 and 37 CFR 404, that the National Institutes of Health (NIH), Department of Health and Human Services, is contemplating the grant of a Start-Up Exclusive Patent License to Biohaven Pharmaceuticals Holding Company having its principal place of business in New Haven, Connecticut. The contemplated license would be for the inventions claimed in U.S. Utility Patent Number 8,859,585, issued October 14, 2014 (filed May 25, 2005), PCT Patent Application Number PCT/US2006/19335, filed May 18, 2006, U.S. Patent Application Number 14/478,442, filed September 5, 2014, European Patent Number 1896025, issued December 28, 2011 (and validated in Germany, France, and the United Kingdom), and Canadian Patent Number 2610025, issued July 22, 2014 (filed May 28, 2006). In addition, inventions claimed in any future applications claiming priority to or benefit of these patents and patent applications would also be subject to any license granted pursuant to this Notice.

The patent rights in this invention have been assigned to the Government of the United States of America. The territory of the prospective Start-Up Exclusive Patent License Agreement may be worldwide and the field of use may be limited to use of scopolamine for treatment of neuropsychiatric indications.

DATE: Only written comments and/or applications for a license that are received by the NIH Office of Technology Transfer on or before [INSERT DATE 15 DAYS FROM DATE OF PUBLICATION IN THE FEDERAL REGISTER] will be considered.

ADDRESS: Requests for a copy of the patent application, inquiries, comments and other materials relating to the contemplated Start-Up Exclusive license should be directed to: Susan Ano, Ph.D., Branch Chief, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 435-5515; Facsimile: (301) 402-0220; E-mail: anos@mail.nih.gov.

SUPPLEMENTARY INFORMATION:

The subject invention describes the use of scopolamine for the treatment of depression, including major depressive disorder. Scopolamine is a known compound that has been employed in the treatment of nausea and motion sickness, as well as in conjunction with analgesics but the suitability of scopolamine for treating depression was unrecognized prior to this invention.

An important feature of scopolamine, as a treatment for depression, is its fast-acting nature. Currently available treatments can be ineffective in certain depression

patients and typically do not show an effect in any patient until four weeks after first administration. However, preclinical data suggests that scopolamine has a rapid, wide-ranging and long lasting effect. This feature makes scopolamine highly desirable as a new treatment for depression.

The prospective Start-Up Exclusive License Agreement is being considered under the small business initiative launched on October 1, 2011 and complies with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404. The prospective exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404. Complete applications for a license in the prospective field of use that are filed in response to this notice will be treated as objections to the grant of the contemplated Start-Up Exclusive Patent License. Comments and objections submitted in response to this notice will not be made available for public inspection, and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: January 13, 2015.

Richard U. Rodriguez, M.B.A.,
Acting Director,
Office of Technology Transfer,
National Institutes of Health.

[Billing Code 4140-01-P]

[FR Doc. 2015-00811 Filed 01/20/2015 at 8:45 am; Publication Date: 01/21/2015]